

K050239



EM Diagnostics
BREASTSCAN TECHNOLOGIES

MAP 16 100

510(k) Summary
EM Diagnostics, Inc.,
EMD Thermography System, Model RTM-02-RES

Date Prepared: 20 February 2006

Sponsor

Mr. Orest Lozynsky
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Consultant

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1151 Hope Street
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Device Name

Proprietary EMD thermography
Name: system, Model RTM-01-
RES

Common Thermography System
Name

Class I device

Telethermographic systems
liquid crystal thermographic systems

Predicate Devices

K003130 SIE-MED Inc.
Regutherrn 952

K971956, CRT 2000 Werner Eidam.
Thermographic Medizin-Technologie
System GmbH

Regulation Number

21 CFR 884.2980
21 CFR 884.2982

Product Code

LHQ
IYM

Obstetrical and Gynecological DevicePanel

Device Description

The EMD Thermography System is an infrared frequency thermography system, designed to provide non-invasive temperature measurements of sites on the human body. The device includes an infrared sensor for measuring temperatures at specific areas on the skin surface. This sensor are placed in contact with the skin to perform measurements. A personal computer and software is for analysis of the temperature measurements and display of the temperature distributions.

Intended Use

The EMD Thermography System is an infrared spectrum thermography system used to measure, record and view thermal patterns generated by the human body. It is intended for use as an adjunct to other clinical diagnostic procedures in the screening and diagnosis of abnormalities where a physician chooses to use thermography.

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Technological Characteristics And Substantial Equivalence

The EMD Thermography System is substantially equivalent to predicate direct contact thermography systems. The EMD Thermography System and the predicate devices have fundamentally the same indications for use. All of these devices are designed to be used to measure temperature.

Performance Testing

Information submitted in this premarket notification for the EMD Thermography System includes results of testing for electrical safety, EMI/EMC, temperature measurement accuracy and results of clinical testing.

Mr. Orest Lozynsky

20 February 2006

Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 - 2008

EM Diagnostics, Inc.
% Mr. James R. Veal
Vice President, Strategic and Technical Assistance
Medical Device Consultant
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K050239

Trade/Device Name: EMD Thermography System, Model RTM-02-RES
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic system
Regulatory Class: I
Product Code: LHQ
Dated: February 20, 2006
Received: February 22, 2006

Dear Mr. Veal:

This letter corrects our substantially equivalent letter of March 16, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Joyce M. Whang".

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K050239

Device Name: EMD-Thermography System, Model RTM-02-RES

Indications for Use:

The EMD Thermography System, Model RTM-02-RES is an infrared spectrum thermography system used to measure, record and view thermal patterns generated by the human body. It is intended for use as an adjunct to other clinical diagnostic procedures in the screening and diagnosis of abnormalities where a physician chooses to use thermography.

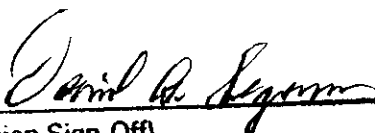
Prescription Use X
(Part 21 CFR 801 Subpart D)

~~AND/OR~~

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050239